

A Compliance Audit of IVF Medical Records: Mapping National and International Standards

Quality begins with a Well-Kept Record.

PRESENTED BY:

Dr. Ashwini Narwadkar
MBA HM 29- 2002

MENTORS:

FACULTY MENTOR: Dr. Ritu Vashishtha
INDUSTRY MENTOR: Dr. Shital Punjabi

INTRODUCTION

- In IVF care, meeting the strict documentation guidelines set by ICMR, ART Act & JCI is essential for improving the quality of care.
- This audit focuses on evaluating the compliance of IVF medical records at Shashwat IVF.
- Although the facility handles a larger volume of routine gynaecological cases, IVF cases were selected for the audit due to their regulatory importance and need for meticulous recordkeeping.

METHODOLOGY

- TYPE OF STUDY: Compliance based descriptive study.
- SAMPLE SIZE: Confidential patient records for IVF procedures from Jan-June 2025.
- SAMPLING METHOD: Availability Sampling
- TOOLS: Customized checklist combined from NABH 6th Ed, JCI 8th Ed, ART Act 2021, ICMR and WHO standards.

ENVIRONMENTAL AND INSTRUMENTATION DOCUMENTATION

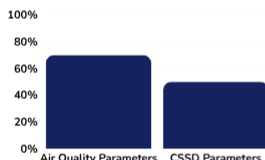
Air Quality Parameters:

- Parameters: Cleanrooms, HEPA filters replacement schedule, VOC levels & Particulate Count.
- Compliance: Partial - VOC monitored for just incubators, HEPA filters checked & updated regularly.
- Gap: No routine air sampling or particle monitoring protocol observed.

Central Sterile Supply

Department Parameters:

- Parameters: Workflow, sterilization packaging, indicators used, log sheets & instrument traceability.
- Compliance: Partial- Workflow followed, log sheet maintained.
- Gap: No chemical indicators, expiry labels, or instrument tracking.



CONCLUSION

- Documentation gaps were found in key aspects through this audit.
- Emphasis needs to be put on the need for standardization across all IVF medical records.
- The findings highlight the necessity for quality enhancement and preparedness for regulatory compliance.

OBJECTIVE

- To assess the degree of conformity of the IVF-related medical records against multiple national & international standards.
- To evaluate the documentation in key procedures, including OPU, ET, ICSI, and IUI.
- To provide actionable suggestions for improving quality and advancing the facility's preparedness for accreditation.

ORGANISATION VISION AND MISSION

VISION:

To be the preferred IVF center for hopeful couples & be known for compassionate care combined with advanced technologies and successful outcomes.

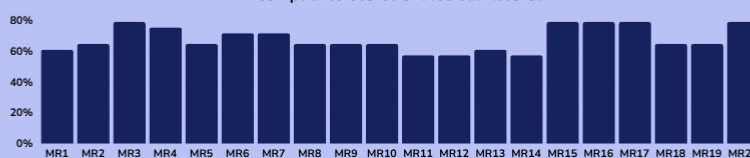
MISSION:

- To provide ethical, evidence based, holistic and personalized fertility care.
- To support patients' journey with respect and empathy.
- To maintain patient confidentiality, improve satisfaction, and encourage continuous quality improvement.

RESULTS

- Valid consent and ART Act mandated IDs were present in 100% of cases, procedure notes and patient friendly language were consistently documented (NABH, ART Act, WHO)
- Witness signatures were incomplete in 65% of records (55% absent, 10% partial).
- 60% of the medical records lacked complete or properly documented discharge summaries, while IVF outcomes and follow-up details were missing in every case.
- Date and time of consent were incomplete in 25% of files (5% absent, 20% partial)
- Documentation issues included overwriting in 15% of the records and patient identification was found to be partial in 10% of files. (JCI, ART Act, NABH)
- Average Compliance Score: 67.68%
- April recorded the lowest compliance performance, with scores falling at or below 60%.
- Highest Compliance Score seen at 78.6% in few records in January & February.

Compliance Scores of Medical Records



PRACTICAL LEARNINGS

- Helped to develop an eye practically for gaps in workflow and documentation taught in classrooms.
- Provided problem solving skills in less structured and real world scenarios.
- Provided hands-on experience with audits, SOP adherence, and coordination issues.

THEORETICAL LEARNINGS

- Provided theoretical understanding of documentation protocols and hospital systems.
- Acquainted with quality and compliance frameworks used during the audit.
- Offered management concepts that guided analysis of team roles and workflow issues.

SUGGESTIONS

- Create & enforce a simplified SOP for consistent documentation.
- Move to fully digital medical records system and add outcome and follow up in them.
- Track the compliances regularly and perform RCA for the drops as and when they happen.
- Implement & enforce formal staff hierarchy for efficient workforce & better outcomes.

MAJOR LEARNINGS

- Acquired practical understanding of operations in a specialized IVF hospital.
- Observed overall impact of individual decisions on departmental workflows.
- Acknowledged the importance of following established standard operating procedures and maintaining high-quality documentation.
- Acquired exposure to multi-department coordination in administrative and clinical processes.
- Realized the crucial contribution of patient-centered care to reproductive health care.
- Identified the value of balancing patient communication (verbal and written) with legal and ethical documentation.

CHALLENGES DURING INTERNSHIP

- Limited digitization of medical records made the data retrieval dependent on the staff.
- Informal staff hierarchies often influence task allocation, leading to confusion about role definitions and blurred lines.
- Duties were assigned ad hoc, making accountability unclear and underwhelming.
- Faced barriers in understanding internal policies as they were not always documented or readily available.

INDUSTRY SECTOR PROFILE

- Shashwat IVF and Women's Hospital, located in Ahmedabad, is a NABH-accredited facility that offers fertility treatments through Assisted Reproductive Technologies (ART).
- Led by Dr. Shital Punjabi and Dr. Rajesh Punjabi, the hospital merges modern technology with personalized care to assist couples on their journey to parenthood.

SWOT ANALYSIS



- STRENGTHS:** Niche Patient Base, Regular Outreach Programs, Holistic Fertility Care, Strong Partnerships
- WEAKNESSES:** Intense Competition, Spatial Limitations Within Facility, Internal Communication Gaps
- OPPORTUNITY:** Technology Upgrade, Enhance Organizational Visibility
- THREATS:** Regulatory Changes, Technological Redundancy

ORGANISATIONAL STRUCTURE



USEFULNESS OF INTERNSHIP

- Helped to develop an eye practically for gaps in workflow and documentation taught in classrooms.
- Gained practical experience of regulatory standards and their application on the ground.
- Provided problem solving skills in less structured and real world scenarios.
- Provided hands-on experience with audits, SOP adherence, and coordination issues.

REFERENCES

- NABH 6th Edition, 2020- AAC Chapter
- JCI Standards for Hospitals 8th Edition, 2024
- ART (Regulation) Act, 2021
- WHO Standards for Health Documentation
- ISO 15189:2022 (Lab Quality)